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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/192,167 11/13/98 MEADE

T A-67412/RFT/

EXAMINER

HM12/0804

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CRANE, J	
ART UNIT	PAPER NUMBER

1623

Handwritten number "4".

DATE MAILED:

08/04/99

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.

09/192,167

Applicant(s)

Meade et al.

Examiner

L. E. Crane

Group Art Unit

1623

---The MAILING DATE of this communication appears on the cover sheet beneath the correspondence address---

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE-----3-----MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, such period shall, by default, expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).

Status

- ☒ Responsive to communication(s) filed on 11/13/98 (application papers) -----
- ☐ This action is **FINAL**.
- ☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- ☒ Claim(s) 1-6 ----- is/are pending in the application.
- Of the above claim(s) ----- is/are withdrawn from consideration.
- ☐ Claim(s) ----- is/are allowed.
- ☒ Claim(s) 1-6 ----- is/are rejected.
- ☐ Claim(s) ----- is/are objected to.
- ☐ Claim(s) ----- are subject to restriction or election requirement.

Application Papers

- ☒ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.
- ☐ The proposed drawing correction, filed on ----- is ☐ approved ☐ disapproved.
- ☐ The drawing(s) filed on ----- is/are objected to by the Examiner.
- ☐ The specification is objected to by the Examiner.
- ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119 (a)-(d)

- ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- ☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been
- ☐ received.
- ☐ received in Application No. (Series Code/Serial Number) -----.
- ☐ received in this national stage application from the International Bureau (PCT Rule 1.7.2(a)).

*Certified copies not received: -----

Attachment(s)

- ☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). ----- ☐ Interview Summary, PTO-413
- ☒ Notice of Reference(s) Cited, PTO-892 ☐ Notice of Informal Patent Application, PTO-152
- ☒ Notice of Draftsperson's Patent Drawing Review, PTO-948 ☐ Other -----

Office Action Summary

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The Group and/or Art Unit location of your application in the PTO has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Group 1600, Art Unit 1623.

- 5 No claims have been cancelled and no preliminary amendments filed as of the date of the instant Office action.

Claims **1-6** remain in the case.

- 10 Claims **1-6** are rejected under 35 U.S.C. §112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

- 15 In claim 1, the terms "an anhydro-nucleoside", "a signalling moiety or signalling moiety precursor", and "an activated anhydro-nucleoside" are generic terms with many possible structural meanings one, some or all of which may or may not be read into the instant claims in view of the total absence of adequate definition of the metes and bounds intended to accompany said terms. For example, with 2-oxo-pyrimidine nucleosides (i.e. uridines and cytidines) there are at least 6 possible different anhydro-forms (2'-O², 3'-O², 5'-O², 2'-C⁶; 20 3'-C⁶ and 5'-C⁶). It is unclear which of these are intended and which are not by reading the instant claim.

- 25 In claim 1, lines 6-7, the terms "cyclization agent" and "cyclized intermediate" are relatively meaningless unless the details of the chemical reaction being alluded to are provided, thereby rendering this portion of the instant claim lacking in adequately defined metes and bounds.

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and bounds intended to accompany said terms. For example, with 2-oxo-pyrimidine nucleosides (i.e. uridines and cytidines) there are at least 6 possible different anhydro-forms (2'-O², 3'-O², 5'-O², 2'-C6; 3'-C6 and 5'-C6). It is unclear which of these are intended and which are not by reading the instant claim.

In claim 1, lines 6-7, the terms "cyclization agent" and "cyclized intermediate" are relatively meaningless unless the details of the chemical reaction being alluded to are provided, thereby rendering this portion of the instant claim lacking in adequately defined metes and bounds.

In claim 2, adding a phosphoramidite moiety to a nucleoside is possible, but where such a group is being added in this case is unclear given the substance of claims 1 and 2.

In claim 3, adding a phosphoramidite-derivatized nucleoside to the terminus of a "growing" nucleic acid appears to make reference to the Caruthers process of nucleic acid synthesis, but remains indefinite for failure to specify the chemical structural variables which define the "phosphoramidite modified nucleoside."

In claim 5, the term "nucleoside analog" is indefinite because applicant has not provided adequate guidance within the instant claim to permit the ordinary practitioner to determine which compounds qualify as a "nucleoside analog" and which do not (an indefinite metes and bounds problem).

In claim 6, the term "carbonydimidazole" is misspelled. Did applicant intend the term to be spelled -- carbonyldiimidazole --?

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Claim 5 is objected to under 35 C.F.R. §1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form.

In claim 5, the term "nucleoside analog" is not a term usually thought to be encompassed by the term "nucleoside", thereby rendering the instant claim lacking in proper antecedent basis. Applicant may introduce by amendment -- further comprising -- language to effectively address this problem or take other appropriate action.

Claims 1-6 are rejected under 35 U.S.C. §112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

In claims 1-6, the chemical reactants are described using generic terms only, thereby encompassing a substantial area of subject matter for which applicant has failed to provide adequate enabling support within the instant disclosure. Specifically terms such as "anhydro-nucleoside" (claim 1), and "nucleoside analog" (claim 5) is directed to a vast array of chemical structures while applicant's specification only discloses a limited number of specific embodiments, leaving the ordinary practitioner the unreasonable burden of determining which claimed embodiments are actually operative and which are not (undue experimentation).

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The following is a quotation of 35 U.S.C. §103(a) which forms the basis for all obviousness rejections set forth in this Office action:

5 "A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made."

10 Claims 1-6 are rejected under 35 U.S.C. §103(a) as being unpatentable over Nexstar '102 (PTO-892 ref. L).

15 The instant claims are directed to a process for making labelled nucleosides from anhydro-nucleosides, for making the phosphoramidites thereof, and for making standard or modified oligonucleotides or polynucleotides therefrom via phosphoramidite coupling.

20 The Nexstar '102 reference discloses processes for making labelled nucleosides from anhydro-nucleosides, for making the phosphoramidites thereof, and for making standard or modified oligonucleotides or polynucleotides therefrom via phosphoramidite coupling. Applicant is referred to pages 17, 21, 23, 26, 3140, 49, 50 and 53, and claim 1, at p. 59, lines 10-11, and claims 5, 20, 22 and 25 wherein the last three claims disclose the nucleoside starting material, disclose the phosphoramidite analogues of the nucleoside, and imply the use of said phosphoramidites to make oligonucleotides incorporating the modified nucleosides by claiming compounds which could be the product of a phosphoramidite oligonucleotidesynthesis.

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Teachings of the prior art which disclose in detail subject matter which reads on the invention as claimed is deemed to render the instant claims lacking in patentable distinction in view of the noted prior art.

5 Therefore, the instant claimed process for making labelled nucleosides from anhydro-nucleosides, for making the phosphoramidites thereof, and for making standard or modified oligonucleotides or polynucleotides therefrom via phosphoramidite coupling, would have been obvious to one of ordinary skill in the art
10 having the above cited reference before him at the time the invention was made.

 References made of record but not cited above are deemed to be either equivalents to the cited references or to be of interest as closely related prior art which shows the state of the relevant prior
15 art.

 Papers related to this application may be submitted to Group 1600 via facsimile transmission(FAX). The transmission of such papers must conform with the notice published in the Official Gazette (1096 OG 30, November 15, 1989). The telephone numbers for the
20 FAX machines operated by Group 1600 are **(703) 308-4556** and **703-305-3592** .

 Any inquiry concerning this communication or earlier communications from the examiner should be directed to Examiner L. E. Crane whose telephone number is 703-~~308-4639~~ . The examiner
25 can normally be reached between 9:30 AM and 5:00 PM, Monday through Friday.

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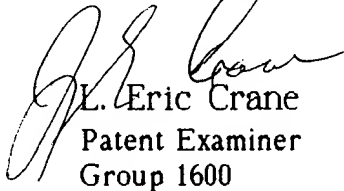
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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor can be reached at (703)-308-1235.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group 1600 receptionist whose
5 telephone number is 703-**308-1235** .

LECrane:lec
8/3/99


L. Eric Crane
Patent Examiner
Group 1600